

# PULMONEX II DOUBLE-TRAP XENON SYSTEM

## OPERATION MANUAL

132-503



**BIODEX**

Biodex Medical Systems, Inc.

20 Ramsey Road, Shirley, New York, 11967-4704, Tel: 800-224-6339 (Int'l 631-924-9000), Fax: 631-924-9241, Email: [info@biodex.com](mailto:info@biodex.com), [www.biodex.com](http://www.biodex.com)

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# Pulmonex II Xenon System



**This manual covers operation procedures for the following product:**

132-503      Xenon System, Pulmonex II, Double-trap, 115 VaC

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






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# Definition of Symbols

*The following symbols and their associated definitions are used and implied throughout this manual.*

Symbol	Definition
	Carefully read these instructions prior to use
	Caution
	General Warning
	General Mandatory Action
	Dangerous Voltage
	“On” Power
	“Off” Power
	Earth (ground)
	Alternating Current
	Fuse
	USB Connector/Cable
	Waste in Electrical Equipment
	Date of Manufacture
	Type B Applied Part
	CE Mark
	CE Mark for products with EC Certificate
	Certified for Safety by ETL Intertek

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# Before Proceeding



**NOTE:** *The warnings, cautions and instructions provided in this manual must be read, followed and kept available for consultation at all times. Observing the information, instructions and procedures presented throughout this manual is essential for using this product both properly and safely.*



## **SPECIFIC CAUTIONS**

- Allow only qualified, trained personnel to operate or service this product.
- If the equipment is used in a manner other than specified in this operation manual, the protection provided by the equipment may be impaired and results could be compromised.
- Never leave patient unattended.
- Disconnect power from source before removing panel or covers. Reliable grounding achieved only by connecting this unit to an equivalent marked hospital only or hospital grade receptacle .



## **EN GARDE SPÉCIFIQUES**

- Permettez au personnel seulement autorisé, entraîné de faire marcher ou assurer l'entretien de ce produit.
- Si l'équipement est utilisé dans une manière autre qu'indiqué dans ce manuel d'opération, la protection fournie par l'équipement peut être diminuée et les résultats pourraient être compromis.
- Ne quittent Jamais le patient sans surveillance.
- Déconnecter la prise secteur avant d'ouvrir le coffret. Une terre fiable ne peut être obtenue que par la connexion à une prise secteur de qualité hospitalière.



**CAUTION:** *Unauthorized modifications to this product are not permitted and will void the manufacturer's warranty. Unauthorized modification of the product may result in a hazard to the user and/or patient. Do not modify this equipment without authorization from the manufacturer.*



**ATTENTION:** *Les modifications faites sans autorisation à ce produit ne sont pas permises et va faire le vide la garantie du fabricant. La modification faite sans autorisation du produit peut s'ensuivre dans un hasard à l'utilisateur et-ou le patient. Ne modifiez pas cet équipement sans autorisation du fabricant.*



**CAUTION:** *Some patients are sensitive to Oxygen. Consult a physician before using Oxygen. If the physician prefers, substitute room air for Oxygen.*



**ATTENTION:** *Certains patients réagissent à l'oxygène. Se référer à un médecin avant d'utiliser de l'oxygène. Utiliser l'air ambiant quand indiqué.*



**CAUTION:** *Do not use humidified Oxygen.*



**ATTENTION:** *N'employez pas l'oxygène humidifié.*

## Training

On-site installation and training is optional. The operation manual includes setup and operating instructions. A training webinar is available on the internet at no charge; questions can be directed to our service department during business hours.

## User Profile

### Patient:

This product accommodates patients fitting the following profile:

- Height: from infants to 78 inches (6 ft, 6 in).
- Weight: up to 500 lb
- Age: infants to adults

### Nuclear technologist:

This product accommodates nuclear technologists fitting the following profile:

- 5th percentile female, 20-65 years of age to 95th percentile male,
- 20-65 years of age

## Product Certifications and Classifications

The Pulmonex II Xenon System has received the following certifications, and falls within the following classifications:

- ETL and cETL listed to UL 60601-1 to CAN/CSA C22.2 No. 601-1-M90, EN 60601-1.
- Class 1, Type B ordinary equipment

## Authorized European Community Representative:



Emergo Europe  
Molenstraat 15  
2513 BH, The Hague  
The Netherlands

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# Important Safety Information



**CAUTION:** Federal Law restricts this device to sale by or on the order of a physician, technologist or other licensed professional.



**ATTENTION:** La Loi Fédérale restreint cet artifice à la vente par ou sur l'ordre d'un docteur, technologue ou d'autre professionnel agréé.



Before using this equipment, read the entire operation manual carefully. Failure to read the manual may result in user error or injury. Be sure to save all provided documents for future reference.



Make certain to understand all warning and caution labels as explained in the Before proceeding section of this manual.



This product should be used only as specified in the operation manual.



The Biodex Pulmonex Xenon System is designed for use in a patient environment.



Biodex Pulmonex Xenon System est conçu à l'utilisation dans un environnement patient.



For product specifications, refer to the table of Contents.



Reference General maintenance procedures in table of Contents.



**CAUTION:** Operation for 132-503: 115 VAC



**ATTENTION:** Opération pour 132-503: 115 VAC



**WARNING:** Only use approved power supplies.



**AVERTISSEMENT:** N'utiliser que les alimentations homologuées



CAUTION: To avoid risk of electric shock, this equipment must only be connected to supply mains with protective earth.



ATTENTION: Pour éviter le risque de choc électrique, cet équipement doit uniquement être connecté à un approvisionnement conduites avec la terre protectrice.



CAUTION: The plug is considered the method of disconnecting the product from main power. Do not place the product in a position where the plug is not easily accessible.



ATTENTION: Le bouchon est considérée comme la méthode de déconnexion du produit d'alimentation. Ne placez pas le produit dans une position où le bouchon n'est pas facilement accessible.



CAUTION: This product is intended to remain in one location during operation. The product is provided with wheels for relocation. Once positioned, engage the locking casters to ensure stability.



ATTENTION: Ce produit est destiné pour rester dans un endroit pendant l'opération. Le produit est fourni avec les roues pour le réendroit. Une fois placé, retenez les roulettes se bloquant pour garantir la stabilité.



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# Biodex Pulmonex II Xenon System Warranty

## 1. Product Warranty

- A. This equipment and its accessories, are warranted by BIODEx MEDICAL SYSTEMS, INC., against defects in materials and workmanship for a period of one year from the date of shipment from BIODEx MEDICAL SYSTEMS, INC. During the warranty period, BIODEx MEDICAL SYSTEMS, INC. will in its sole discretion, repair (on-site), send replacement parts or replace the equipment found to have such defects, at no charge to the customer.

EXCEPT AS STATED ABOVE, THERE ARE NO WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OR MERCHANTABILITY OR FITNESS FOR USE. BIODEx DOES NOT ASSUME LIABILITY FOR INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES INCLUDING LOSS OF USE, SALES, PROFITS OR BUSINESS INTERRUPTION.

- B. This warranty does not apply if the product, as determined by BIODEx MEDICAL SYSTEMS, INC., is defective due to abuse, misuse, modification or service performed by other than a BIODEx MEDICAL SYSTEMS, INC. authorized repair representative. Misuse and abuse include, but are not limited to, subjecting limits and allowing the equipment to become contaminated by fluid materials.
- C. In order to obtain warranty repair service and to expedite repair process, please contact BIODEx MEDICAL SYSTEMS, INC. Support Services Dept. at 800-224-6339, and select Radiology product support as prompted.

## 2. Warranty is non-transferable.

## 3. Non-Warranty Service

- A. Repairs and/or replacements not covered by this warranty may be performed by BIODEx MEDICAL SYSTEMS, INC. authorized service representatives.
- B. The cost of transportation to and from the service location will be the responsibility of the customer.

**NOTE:** Activate your product warranty. Register online @ [www.biodex.com/warranty](http://www.biodex.com/warranty)

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# Service Support

If you think you have a service problem, take the following action:

1. Check to see that the problem occurs more than once.
2. Refer to the instruction manual and operations procedure.

If you still think you have a service problem, call BIODEX MEDICAL SYSTEMS, INC., Service Department at (800) 224-6339 and select radiology product service as prompted.

Keep yourself and the phone next to the equipment.

1. Service will ask you for a brief description of the problem. We will ask specific questions about the malfunction that occurred. This diagnostic process may take a few minutes, so call us when you can set aside an uninterrupted block of time.
2. After taking the information, we will advise on the action we will take.
3. Sometimes service personnel must consult with engineering and it may take time to get back to you. Be sure to let the service representative know your schedule so that we can call at a convenient time.
4. The return call may be from a person other than whom you first reported the problem to.
5. After analyzing the problem, we will decide if the unit can be repaired on site, or replacement parts will be sent.
6. If the unit must be returned, it will be given a Return Materials Authorization Number (R.M.A. #) by us. Pack the system in the carton that it was originally shipped in, or pack it safely and securely to avoid shipping damage. It is the customer's responsibility for any damage that occurs during shipping.
7. Non-warranty/non-service contract charges for repair are as follows:
  - a. Materials
  - +  
b. Time
  - +  
c. Travel Zone



## Contact Information

Biodex Medical Systems, Inc.  
20 ramsey road, Shirley, new York, 11967-4704  
Tel: 800-224-6339 (int'l 631-924-9000)  
Fax: 631-924-8355  
Email: [supportservices@biodex.com](mailto:supportservices@biodex.com)  
[www.biodex.com](http://www.biodex.com)

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# 1. Introduction

## Intended Use

The Pulmonex II Xenon System was designed for the safe delivery and trapping of Xe-133 to a patient. It is shielded for patient and operator safety. The design features are intended to provide maximum, reliable test results.

Before using the Pulmonex II on an actual patient, we suggest making several dry runs through the following operation procedures (without using xenon). Having become familiar with the operating routine, ask a colleague to stand in as a practice patient and try the procedures again. Once you feel fully comfortable operating the Pulmonex II, you will be able to perform xenon studies on any patient with complete confidence.

## Indications for Use

The Pulmonex II Xenon System is typically used in a nuclear medicine department, diagnostic imaging centers and private practice clinics to achieve quality lung images.

Internal systems of the Pulmonex® II are shielded for patient and operator safety. The system features two built-in gas traps that operate with a blower fan. Exhaled xenon is pulled through activated charcoal housed within two .125" lead shielded "u"-shaped traps. The double traps extend the life of your charcoal and provide a lengthy migration path for xenon effluent, allowing greater decay and absorption before exhaustion. A cartridge containing drierite serves as a moisture absorber for air passing into the trap. The charcoal trap can then more effectively remove xenon effluent after each study. Airflow regulation of the trap pump assures complete patient and system washout. Averaging 30-50 studies per month, the charcoal trap will last approximately one year; charcoal traps are easily replaced.

A disposable bacteriostatic filter, used in conjunction with a disposable mask or mouthpiece, prevents system contamination.

**NOTE:** *Because the Pulmonex II uses a temperature-sensitive valve which must acclimate to the immediate environment, the system must reside for several hours in the department where it will be used prior to performing any studies.*

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## 2. Setup Procedure

(See Figures 1 - 7.)

1. Open lower front door. All hoses should be connected to their respective ports. (see figure 1.)
2. Open the top door. The Pulmonex II can use either of two different style Drierite cartridges. A refillable plastic cartridge is shipped with your unit and is located on the right side of the compartment. You can fill this cartridge to one-third full with loose Drierite (catalog #139-101). Alternatively, you can remove this cartridge and replace it with the sample pre-filled single use cartridge included in the sample Xenon Disposable Convenience Kit supplied. In either case, the disposable mixture of blue and white Drierite crystals prolongs charcoal trap life span. Failure to change the moisture absorber regularly will significantly shorten the life span of the charcoal trap; therefore, it is recommended that it be changed after every study. (see figure 2.)

**NOTE:** The flow arrow on the pre-filled Drierite cartridge should match the flow label in the Pulmonex II cabinet.

3. Located on the left side of the top compartment is the Soda-Lime cartridge. This cartridge serves as a carbon dioxide trap. You can fill this cartridge to one-third full with loose Soda-Lime (catalog #130-019). Alternatively, you can remove this cartridge and replace it with the sample white pre-filled single use cartridge included in the sample Xenon Disposable Convenience Kit supplied. In either case, the Soda-Lime cartridge helps stop the breakdown of Soda-Lime granules that may possibly clog the 10-way valve and hinder patient air flow. Failure to change the Soda-Lime regularly could cause the patient to hyperventilate. Therefore, it is recommended that you change it after every study.

**NOTE:** The flow arrow on the pre-filled Soda-Lime cartridge should match the flow label in the Pulmonex II cabinet.

4. Relocate the unit to the area of operation. Ensure the power switch and the timer are OFF. Plug into a nearby electrical outlet.
5. At the rear of the unit, there are two black hose connections positioned side by side (see figure 3.) The blue hose adapters in the open ends of hoses should be removed to connect to these fittings. The blue adapters are required to connect to the Hans Rudolph Valve and to older Pulmonex systems only. Attach the 1.125" bore hose and Hans Rudolph Valve assembly to the hose connectors so that air flows into the Hans Rudolph Valve on the left and out from the Hans Rudolph valve on the right. (see figure 4.) The green dot sticker on the Hans Rudolph Valve faces up when connected. (see figure 5.) Connect the bacteria filter directly to the Hans Rudolph Valve. Attach either a face mask or mouthpiece directly to the bacteria filter. (see figure 6.)

**Figure 2.** The Carbon Dioxide



**Note:** If you require longer tubing for your patient, you can attach a tube to the bacterial filters and then connect the mouthpiece or mask to this hose.

**Note:** Keep the breathing tubes as short as possible. (See "Troubleshooting" section on Strong Breathing Resistance.) For supine patients, bring the system as close as possible to the Bedside. As a safety precaution you can connect a hose from your room vent to the exhaust port located just below the overhang on the patient side of the Pulmonex II. Do not leave this connected all the time. It will shorten the life of the traps.



**Caution:** Some patients are sensitive to Oxygen. Consult a physician before using Oxygen. If the physician prefers, substitute room air for Oxygen.



**Attention:** Certains patients réagissent à l'oxygène. Se référer à un médecin avant d'utiliser de l'oxygène. Utiliser l'air ambiant quand indiqué.

6. To add Oxygen, connect and clamp a .25" Oxygen hose from your supply to the Oxygen inlet port on the Pulmonex II front panel.



**Caution:** Do not use humidified Oxygen.



**Attention:** N'employez pas l'oxygène humidifié.

7. Ensure that the shipping cap is removed from the exhaust port located on the lower cabinet on the rear of the unit (facing the patient).
8. In the lower cabinet is a plug socket that the power pack for the xenon monitor can plug into. This socket receives power as long as the power switch to the Pulmonex is ON. Do not plug anything but the xenon monitor into this socket. (See Figure 7.)



Figure 4.



Figure 5.



Figure 6.



Figure 7.

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## 3. Performing a Study

(See Figure 8)

**NOTE:** Oxygen input should not exceed eight psi with regulator. Oxygen input, with a flow rate meter, should be six to eight liters/minute, not to exceed 10 liters/minute.

1. Using a source, position the patient in front of the scintillation camera. Ensure both lungs are within the crystal area.
2. Set the camera for Xe-133. Be prepared to record all data after xenon injection.
3. Turn the Power Switch, located on the patient side of the unit, to ON. (0 is OFF, 1 is ON.)

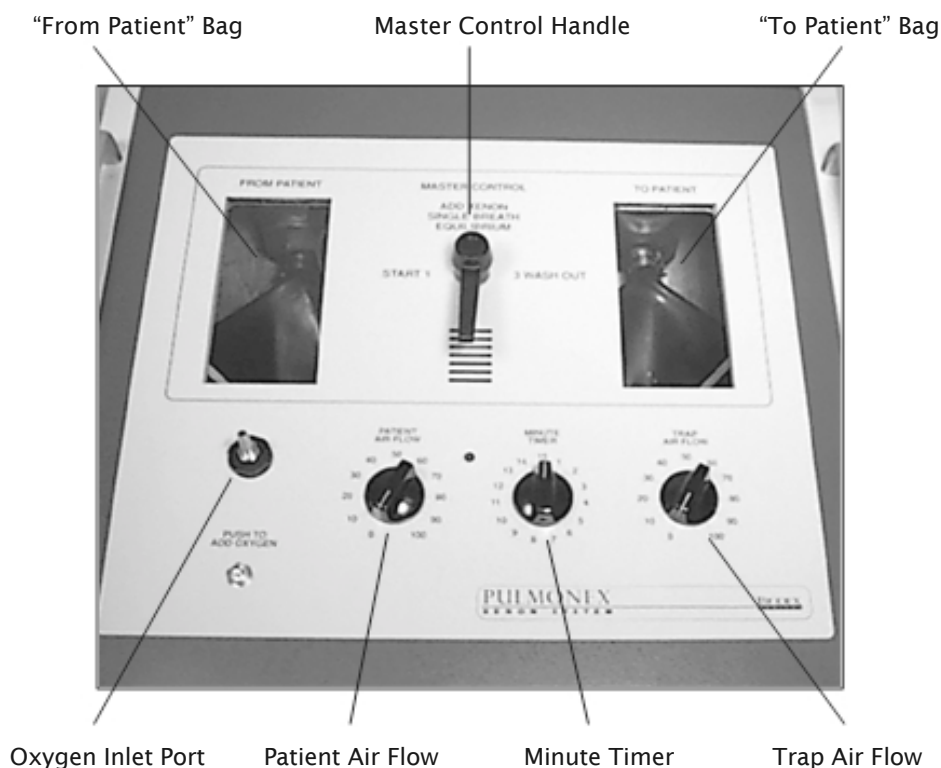
**NOTE:** even after the Power Switch is set to the ON position, power will not be evident until the Timer has been turned ON.

4. Place the Pulmonex II as close to the patient as possible and set the pointer on the master control handle to "Start" position #1.
5. Set "Patient Air Flow" control to 30 (an arbitrary figure that can be changed to accommodate the patient's breathing pattern). Set "Trap Air Flow" control to "0".
6. Press the button on the front panel to add Oxygen to the "To Patient" bag. Only add a small amount of Oxygen, about one quarter full. (the bag will only move slightly, do not fill it up.) More Oxygen can be added later if it is required for the patient. In many cases, it is possible not to add any Oxygen and perform the entire study on ambient air. In all cases, the Oxygen is only to enrich the air in the circuit.

**Note:** To perform a study using ambient air, turn the Pulmonex II on using the timer and proceed to set the handle to the "Single Breath, Equilibrium" position #2 before connecting the patient to the system. When the "To Patient" bag is one-quarter full, switch the handle back to position #1. To add ambient air, turn the Air Flow up to 100, add the desired volume, and turn the Air Flow back to 30. The system is now ready to use.

7. Make sure the system is in "Start" position #1.
8. Set the timer to nine minutes (an arbitrary figure that can be changed at any time depending on the study procedure).
9. Remove the face mask or mouthpiece from the tubing.
10. Place the face mask over the patient's face and attach mask retainer or mouthpiece and nose clip. Have the patient breathe to get accustomed to the face mask.
11. With the handle in the "Start" position #1, connect the mask to the hose. Instruct patient to breathe briefly while becoming accustomed to the face mask and tubing. The "From Patient" bag will move slightly as the patient exhales.
12. Switch the handle to "Single Breath, Equilibrium" position #2. Use either an injector gun or a syringe filled with xenon, and puncture the injection site of the face mask, mouthpiece or direct dose adapter. Add xenon as the patient takes a deep breath. Instruct patient to hold breath for as long as possible. After exhaling, the patient should resume normal breathing while you increase the "Patient Air Flow" control to 40 (an arbitrary figure that can be changed to accommodate the patient's breathing pattern).

Advise the patient to breathe normally. Observe breathing bags moving through the front panel windows. Add Oxygen if necessary for patient comfort.



**Figure 8.**

**NOTE:** Patients with a large lung capacity or breathing faster will require a higher patient air flow speed (i.e.: 50) or higher. Do not make it too high or the patient will not be able to inhale.

**NOTE:** If the xenon is not getting to the patient for single breath, on future studies lower the "Patient Air Flow" control to 10 or 20 for approximately five seconds before xenon administration. Instruct the patient to exhale and add the xenon while the patient inhales.

13. Once the patient reaches equilibrium (one to two minutes, the counting rate on the camera stabilizes), switch to "Washout," position #3. Turn the Trap Air Flow Control to 50 about 10 seconds before going to Washout. Take washout data on the camera (typical framing: first image, 15 seconds; second, 30 seconds; third, 60 seconds). Have the patient breathe normally.
14. Carefully watch the "From Patient" bag. if it starts blowing up, the patient is breathing too fast. Advise normalized breathing and increase the "patient air Flow" speed. If the bag continues to expand up towards the glass, the patient will feel back pressure and resistance. to relieve this effect, increase "Trap Air Flow" by turning the Trap Flow knob clockwise until the breathing bag deflates. Return the control to approximately one-half of its range when the study is complete. The use of this trap motor control will be a rare occurrence. Do not adjust unless absolutely necessary and be sure to return it to its original position. To be effective, the increase in motor speed must be accomplished before the bag is full, thus, it is vital to watch the "From Patient" bag carefully during washout.

**NOTE:** If the motors are running too fast it may be difficult for the patient to breathe in.

15. When the washout is complete, remove the patient from the system. Allow the system to run for a few more seconds or until both bags are empty.

## 4. Maintenance

### General Maintenance Procedures

1. Biodex recommends that the moisture absorber and the Soda-Lime (CO<sub>2</sub> absorber) be changed after every study. Once granules change color, efficiency is already compromised. Absorber granules can also break down in size; the smaller granules and powder will potentially clog the system, hinder patient air flow and damage system circuitry. Biodex offers moisture absorber and Soda-Lime for refillable cartridges and in pre-filled disposable cartridges. Visit our Xenon Disposables section At [www.biodex.com/lungventilation](http://www.biodex.com/lungventilation).



2. Administer the xenon as close to the patient as possible. Having the xenon enter the patient near the face mask or mouth piece ensures a good bolus for single breath. (see figure 9.) We recommend using an injection adapter as close to the patient as possible.



Biodex carries an entire line of disposable xenon kits, some with injection adapters, with luer lock fittings, or injection ports (see catalog). These options will allow the use of a xenon gun, xenon injection dispenser or syringe directly in line with the patient's breathing passage.

3. Test the trap effluent on a regular basis. Keep a formal record according to NRC, state or local regulations. The easiest and most efficient way to test the trap is by using the xenon Trap Monitor (#136-755). If you do not have a monitor, refer to the Leak and Trap Test procedure explained later in this manual.
4. Periodically remove the two breathing tubes from the back of the unit. Take one tube and connect it to both ports, forming a C configuration. Place the handle in position #2 and press the Oxygen button until the bags are full and tight up against the glass windows. They should remain full for approximately two minutes. If they sag or fail to blow up tight, the system may have a leak. Refer to the Leak and Trap Test procedure as explained later in this manual.
5. All rubber products such as the breathing bags deteriorate over time. Periodic inspection and replacement is required. Storage, usage and environmental factors will affect the useful life of the bags. We recommend performing a routine visual inspection and system leak test as outlined above in step 4 to insure the integrity of the breathing bags and system.

**NOTE:** Biodex recommends that the (two) breathing bags (130-610) be changed every three years. Breathing bags should be inspected periodically for signs of deterioration such as swelling, tackiness, or cracking. If any of these conditions are observed based on visual inspection and leak test results, replace bags immediately.



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## Maximizing Charcoal Trap Efficiency

in a Dual trap System, it is recommended that the charcoal trap (#132-319) on the right side be replaced every 12 months. move the left side trap to the right side and place the new trap on the left side. to maximize trap effectiveness, follow these guidelines:

1. Once the patient has completed the washout, do not leave the system running for more than 30 seconds.
2. Monitor the trap air flow blower motor. It should be set at a maximum of 50-60 and only increased when a patient needs assistance during washout.
3. Change the moisture absorber after every study!

**NOTE:** Do not leave the Pulmonex II in position #3 when not in use.

## Charcoal Trap Replacement Procedure

To Replace the Charcoal Trap:

1. Remove the right side trap.
2. Move the left trap to the right position.
3. Install the new trap on the left side.

**NOTE:** Change the right trap side annually for average use.

## Upper Blower Replacement

*Tools Required: medium size blade screwdriver and 5/32" hex Tool*

1. Using a 5/32" hex tool screwdriver, remove two hex screws from the rear of the upper panel. Then remove two screws from the upper panel behind the front drop down door.
2. With the top panel loose, you may prop up the panel from the rear of the unit using a 12-inch block of wood. This will provide access to the upper blower.
3. The blower is located on the underside of the front panel left side location.
4. Locate blower and remove two hoses (note orientation) and disconnect electrical connector. (see figure 10.)
5. Using blade screwdriver, unfasten snap ring bracket by inserting blade in slot and twist. Remove blower.
6. Replace blower snap bracket, reattach hoses (note orientation), reconnect electrical connector.
7. Test for proper operation.
8. Replace cabinet front panel and secure with four screws.

If you have additional questions, contact Biodex Support Services at 1-800-224-6339 or 631-924-9000, ext. 2124 or ext. 2125.

## Lower Blower Replacement

*Tools Required: medium size blade screwdriver*

1. Locate blower in lower cabinet on the back wall.
2. Remove hoses (note orientation), disconnect electrical connector.
3. Using a blade screwdriver, unfasten snap ring bracket by inserting blade in slot and twist. Remove blower.
4. Replace blower snap bracket, reattach hoses (note orientation) reconnect electrical connector.
5. Test for proper operation.

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## Leak Test

The following procedures are a simple yet effective means of testing the delivery and breathing portion of the Pulmonex II system for leaks. Tests A and C should be done with the Pulmonex II turned OFF.

### Test A

(Be sure Pulmonex is turned OFF.)

1. Connect one hose between the "To Patient" port and the "From Patient" port located on the patient side of the system.
2. With the system in position #2 and the oxygen supply connected, depress the "Add Oxygen" button on the front panel of the system and fill until both bags are full and pressed up against the front viewing windows.
3. Turn OFF the Oxygen supply. listen carefully for any leaks (the bags should remain full for at least one minute.) if no leak is found, empty the bags and replace outside hoses and fittings.

### **If a Leak is Suspected**

Remove the four screws that hold the front panel in and raise the panel slightly. Now feel inside for any leaks.

### **If a Leak is Found in a Hose**

Replace the entire section. Occasionally one of the breathing bags will tear or a hole will develop. These bags are Biodex Medical Systems (catalog #130-610) and are easily replaced. If the leak is in one of the fittings, they can be easily sealed with silicone.

**NOTE:** *If you suspect a leak but it is proving hard to find, move on to test B.*

### Test B

(Turn Pulmonex ON.)

1. Connect one hose between the "To Patient" port and the "From Patient" port located on the patient side of the system.
2. Empty both bags by putting into position #3.
3. Put system in position #1.
4. If the "To Patient" bag blows up, very carefully check to see if the fitting connecting the blower to the blue adapter on the 10-way valve is broken.
5. If it is, run a bead of silicone around the fitting to seal it and let dry.
6. Now try steps #2 through #4 again. If the bag does not fill, repeat the leak test (Test A).
7. If the bag fills, call Biodex Medical Systems to replace the 10-way valve (catalog #132-515).

### Test C Oxygen Button Valve Leak Test

(Be sure Pulmonex is turned OFF.)

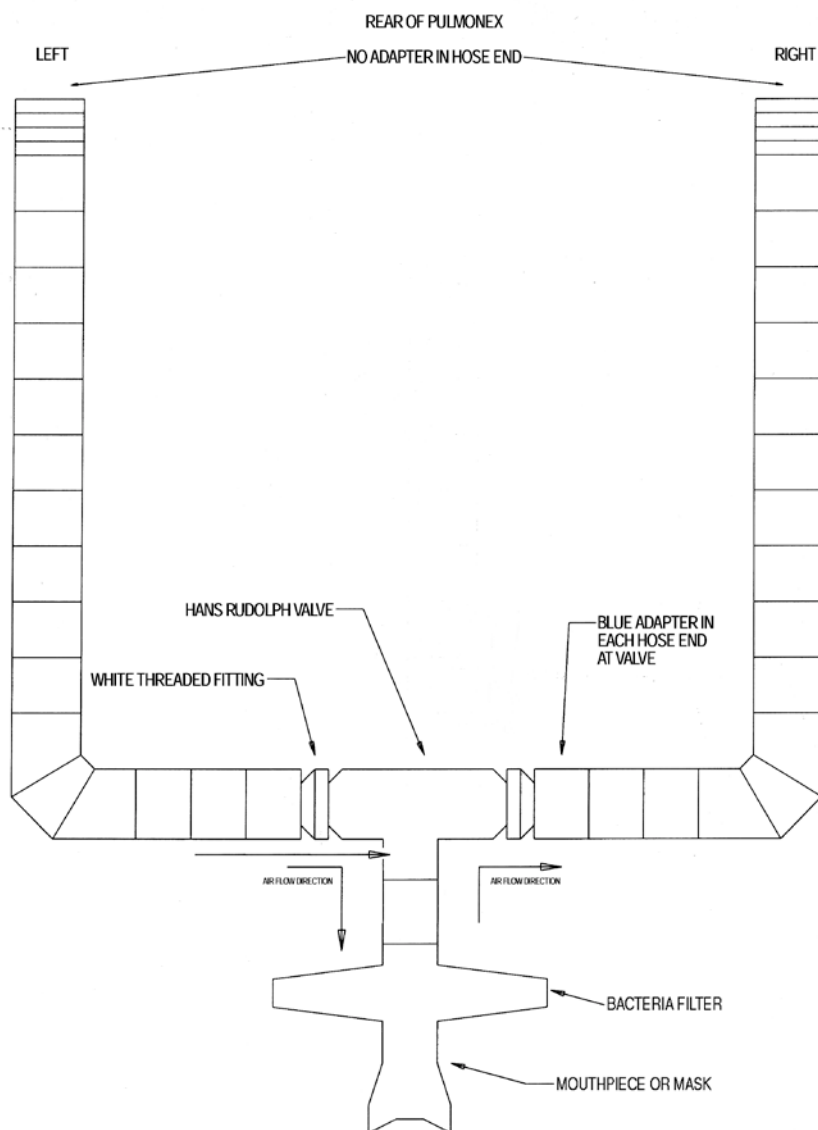
1. With a hose connecting the two patient ports, connect the Oxygen supply and turn it on.
2. If the "To Patient" bag fills without depressing the "Add Oxygen" button, this valve needs to be replaced.

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## Hose Set Up

(See Figure 6 and Figure 11)

1. Hose
2. Hans Rudolph Valve - attach so that air flows in on the left and out on the right; green dot sticker faces up.
3. Bacteria filter
4. Face mask or mouthpiece placed directly onto the filter - you may add an injection adapter between the filter and mask or mouthpiece.



**Figure 11.** Pulmonex Tubing Setup

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## Manual Trap Test (Without Monitor)

Trap exhaust is monitored by using the gamma camera without a collimator.

The following simple technique is used:

1. Remove the collimator from the camera.
2. With a five percent window, calibrate for Xe-133.
3. Fill a large plastic bag with a known volume of air (example, 25 liters).
4. Inject a known quantity of xe-133 (such as 100  $\mu\text{Ci}$ ) into the bag. The concentration will be  $4 \times 10^{-3} \mu\text{Ci}/\text{cm}^3$ .
5. Place the bag in front of the crystal and count for a known period of time. The counts per minute (cpm) obtained is a measure of the efficiency.
6. Collect the exhaust of a typical study in another bag of the same volume (25 liters) and count as defined in step #5.
7. Ratio the count rates to the standard taken to determine exhaust concentration.

Example: If  $4 \times 10^{-3} \mu\text{Ci}/\text{cm}^3$  yields 600,000 cpm above the background and collected effluent from the patient study was 150 cpm above the background, then:

$$\text{Ratio} = \frac{1.5 \times 10^2 \text{ cpm}}{6 \times 10^5 \text{ cpm}} = 2.5 \times 10^{-4}$$

$$\begin{aligned} \text{Exhaust Concentration} &= r (2 \times 10^{-3} \mu\text{Ci}/\text{cm}^3) \\ &= (2.5 \times 10^{-4}) (4 \times 10^{-3} \mu\text{Ci}/\text{cm}^3) \\ &= 1 \times 10^{-6} \mu\text{Ci}/\text{cm}^3 \end{aligned}$$

\* MPC Xe-133 controlled areas should not exceed  $1 \times 10^{-5} \mu\text{Ci}/\text{cm}^3$

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## 5. Troubleshooting

### PROBLEM/PROBABLE CAUSE

### SOLUTION

#### NO POWER

Timer not on	Turn timer on
Power cord cut or broken	Replace cord
No power in outlet	Try different outlet
Incorrectly connected the transformer	Connect properly
ON/OFF switch is OFF	Turn switch to ON (1)

#### OXYGEN NOT GETTING INTO SYSTEM

Tank or oxygen supply empty	Refill tank
Flow rate on tank not set high enough	Turn flow rate up
Not holding oxygen button down long enough	Button must be depressed for the whole time oxygen is to be added
Internal one-quarter hose has come off fittings	Reattach hose and re-clamp

#### XENON NOT GETTING TO PATIENT FOR SINGLE BREATH

Injection not near the patient	Change injection location to a location closer to the patient
Injected when patient exhaled	Inject after patient exhales and starts inhaling
Patient air flow speed set too high	Turn blower speed down to 20 if xenon is being drawn into system at least 15 seconds prior to injection of xenon
Blower speed not set high	After injecting xenon, blower patient air flow speed should be raised to at least a setting of 40, higher if necessary
Soda-lime and Drierite cartridges more than one-third full	Cartridges should not be filled too full
Not enough oxygen supplied	Add more oxygen (it can be added at any time during the study.)
Too much oxygen put into the "to patient" bag to start study	Only fill "To Patient" bag one-third full with Oxygen
Study runs too long	Shorten length of study. Equilibrium should not take any more than five to six minutes.
External hose cracked	Replace hoses

#### XENON NOT GETTING TO PATIENT FOR SINGLE BREATH/EQUILIBRIUM

Gun clogged	Check gun
Injected xenon in position #1 (start)	Inject in position #2
Main valve core not turning when handle is turned	Call Biodex Medical Systems
Bacterial filter absorbs xenon	Change filter type to recommended filters supplied by Biodex Medical Systems
System leaks	See leak test
Patient hose set not set up properly	Correct Hans Rudolf Valve and hoses for proper directional flow
Is camera set for xenon?	Set camera for xenon

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### **“TO PATIENT” BAG FILLS DURING STUDY**

Leak around face mask or nose clamp when mouthpiece is used    make sure face mask retainer is tight.

	Make sure there is a tight seal around the mouthpiece and that nose clamp is being used
External hose cracked	Replace hose
Blower to 10-way valve fitting broken	See Test B
Oxygen valve leaks	Replace Oxygen valve (See procedure to test for leaks, Test C)

### **LOW COUNTS THROUGHOUT STUDY**

Vial not completely emptying	Check vial before and after study
Not enough xenon to start study	Use bigger dose of xenon
Gun clogged	Check gun

### **LOSING COUNTS**

Nose clip not being used with mouthpiece	Use nose clip
Leak around mouthpiece or face mask	Make sure mask retainer or mouthpiece is secured properly
Cracks in external hose	Replace hose
Bacteria filter is absorbing xenon	Use Biodex Medical Systems recommended bacteria filters (check filter for activity)
Plug-in injection fitting is not capped	Cap luer lock plug-in injection fitting

### **STRONG BREATHING RESISTANCE**

Hoses are too long	Reduce length of tubing to 24" maximum for blue corrugated tube or 36" for 1-1.125" smooth-bore hose. Use tubing as short as possible.
Hoses on patient's side of Hans Rudolph Valve	Remove hose. Bacteria filter and face mask should be affixed directly to Hans Rudolph Valve.
Hans Rudolph Valve (Y or t style) is upside down	Hans Rudolph Valve should be attached so that air flows in on the left and out on the right. Green dot sticker faces up.
One-way valves sticking	Replace Hans Rudolph Valve
Blowers running too fast	Reduce blower speed

### **“FROM PATIENT” BAG NOT EMPTYING DURING WASHOUT**

Shipping cap not removed from exhaust port	Remove cap from exhaust port
Patient air flow blower speed set too low	Turn speed up to 60, higher if necessary
Trap air flow blower speed set too low	Generally, the trap air flow cabinet blower speed is set at 50, however, on some patients it will have to be turned up
Blowers not running	Check power or replace blower
Breathing bags crimped	Uncrimp bags
Charcoal has settled in lead cartridge	Remove cartridge, turn upside down and shake gently, then replace cartridge

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**TRAP LEAKING XENON**

Monitor not working	Check trap effluent manually
Crack in seam of cartridge	Seal with silicone
Loose fittings on cartridge	Seal fitting with silicone
Crack in hose to trap or hose is not attached	Replace or reconnect hose
Cartridge saturated	Replace cartridge
Charcoal has settled	Shake cartridge gently to loosen charcoal

**OXYGEN HOSE COMES OFF**

Input pressure too high	Adjust input pressure to not greater than 8 psi
No clamp for hose at input fitting	Install clamp

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## A. Appendix A - Specifications

**Dimensions:** 48.5" h x 22" depth x 20.5" w (123.2 x 55.9 x 52.1 cm)

**Motor:** UL approved. 12 volt DC

**Electrical Requirements:** 115 VAC, 1 amp, 50/60 Hz

**Casters:** locking

**Shipping weight:** 375 lb (172.5 kg)

**Certifications:** ETL and cETL listed to UL 60601-1 to CAN/CSA C22.2 No. 601-1-M90, EN 60601-1

**Warranty:** one year parts and labor



*Authorized European Community Representative:*



Emergo Europe  
Molenstraat 15  
2513 BH, The Hague  
The Netherlands



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## B. Appendix B - Conformance to Standards

This equipment conforms to the following safety standards:

<b>Standard</b>	<b>Edition and/or date</b>
IEC60601-1-2	1993

*Table 1.1. Safety standards*

### Accompanying EMC Documents

this medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

- Portable and mobile RF communications equipment can affect medical electrical equipment.
- Use of accessories, transducers and cables other than those specified, with the exception of accessories, transducers and cables sold by the manufacturer of this equipment, as replacement parts for internal and external components, may result in increased emissions or decreased immunity of the equipment.
- The Pulmonex should not be used adjacent to or stacked with other equipment. If the Pulmonex is used while positioned adjacent to other equipment, it should be observed to verify normal operation in the configuration in which it will be used.

### List of Cable Accessories

The list in Table 1.2 includes all accessory cables supplied with the Pulmonex for which the manufacturer of this equipment claims compliance to EN 60601-1-2 when used with the Pulmonex.

<b>Cable description</b>	<b>Part no.</b>	<b>Cable length</b>
Power Cable	Biodex # 945-110-e730	10ft

*Table 1.2. Pulmonex cable*

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## Declaration of Conformity


### Emissions

<b><i>Manufacturer's declaration electromagnetic emissions</i></b>		
The Pulmonex is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulmonex should assure that it is used in such an environment		
<b>Emission test</b>	<b>Compliance</b>	<b>Electromagnetic environment</b>
RF emissions EN 55011	Group 1	The Pulmonex generates RF energy only for its internal functions. Therefore, its RF emission is very low and is not likely to cause any interference in nearby electronic equipment  The Pulmonex is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network supplying buildings used for domestic purposes.
RF emissions EN 55011	Class B	

## Immunity

### ***Manufacturer's Declaration Electromagnetic Immunity***

The Pulmonex is intended for use in the electromagnetic environment specified below. The customer or the user of the Pulmonex should assure that it is used in such an environment.

<b><i>Immunity test</i></b>	<b><i>IEC 60601-1-2 Test level</i></b>	<b><i>IEC 60601-1-2 Compliance level</i></b>	<b><i>Electromagnetic environment - guidance</i></b>
Radiated RF IEC 801-3:1991	3 V/m, 26 MHz to 1000 MHz	3 V/m, 26 MHz to 1000 MHz	<p>Portable and mobile RF communications equipment should be used no closer to any part of Pulmonex, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance:  <math>d = 1.2 \sqrt{P}</math> 26 MHz to 1000 MHz            where P is the maximum output power rating of the transmitter in watt (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters(m)</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup> Interference may occur in the vicinity of Equipment marked with the following symbol:</p> 

**Note 1.** UT is the a.c. mains voltage prior to application of the test level.

**Note 2.** At 26 MHz and 1000 MHz, the higher frequency range applies.

**Note 3.** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflections from structures, objects and people

<sup>a</sup>Field strength from mixed transmitters, such as base stations for radio telephones and land mobile radios, amateur radio, AM or FM broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Pulmonex is used exceeds the applicable RF compliance levels above, the Pulmonex should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Pulmonex .

<sup>b</sup>Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

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## Recommended Separation Distances

***Recommended separation distances between portable and mobile RF communications equipment and the Pulmonex. Table 6***

The Pulmonex is intended for use in the electromagnetic environment in which radiated RF disturbance are controlled. The customer or the user of the Pulmonex can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the Pulmonex as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
		26 MHz to 1000 MHz $d = 1.2\sqrt{P}$	
0.01		0.12	
0.1		0.38	
1		1.2	
10		3.8	
100		12	

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters(m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

**Note 1.** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

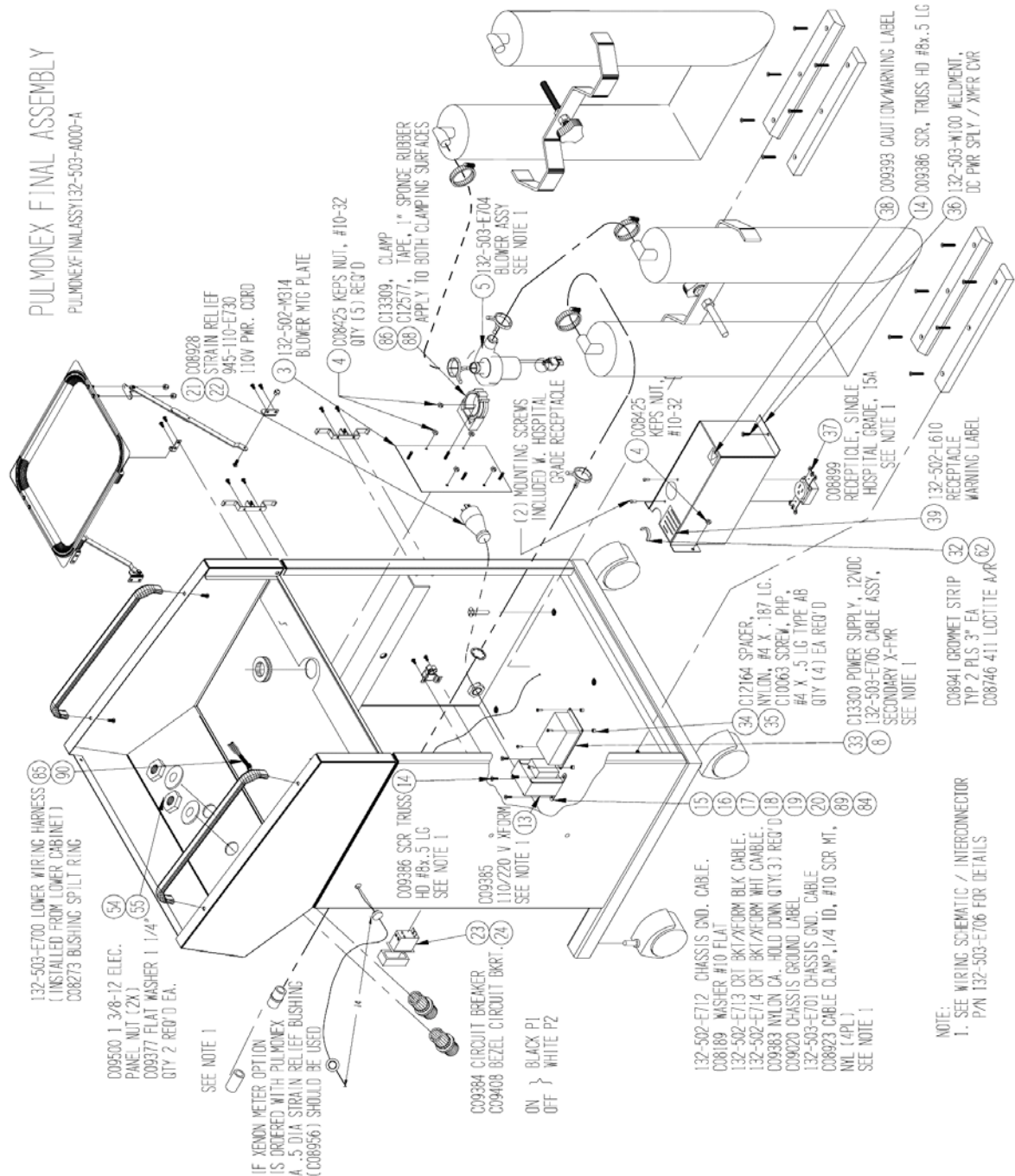
**Note 2.** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

## Operating Temperature

Do not expose the equipment to a temperature change of more than 5° F (3° C) per hour.

limits of low and high operating temperature ranges are 59° to 86° F (15° C to 30° C).

# C. Appendix C - Schematics



# PULMONEX FINAL ASSEMBLY

PULMONEXFINALASSY132-503-4000-A

(47) 132-502-M300 TRAY WELDMENT  
C09363 SCR, BTN HD 8-32x.312 QTY 4 REQ'D  
C08002 LOCITITE BLUE A/R

(44) C09366 SCR, BTN HD 8-32x.312 QTY 4 REQ'D  
C08002 LOCITITE BLUE A/R

(87) C09365 SCR, BTN HD 10-32x.375 QTY 8 REQ'D  
C08002 LOCITITE BLUE A/R

(61) C08002 LOCITITE BLUE A/R

(46) C08690 ACORN NUT, #8-32 QTY 4 REQ'D  
C08002 LOCITITE BLUE A/R

(45) C09364 TRAY SUPPORT, L.H.

(46) C08689 ACORN NUT, #10-32 QTY 2 REQ'D  
C08002 LOCITITE BLUE A/R

(43) 132-502-M311 LOWER TRAY MFG BRKT QTY 2 REQ'D

(28) C08615 HEX NUT, 1/2-13 QTY 2 REQ'D  
C08002 LOCITITE RED A/R  
NOTE: LOCITITE RED ON STOP NUT ONLY, POSITION 3/4" FROM KNOB

(27) 132-502-M318 THREADED ROD 2PL  
NOTE: SECURE CARTRIDGE TO INSIDE CABINETS SIDE WALL

(30) 132-319 LEAD CARTRIDGE ASSEMBLY QTY 2 REQ'D

(29) 132-502-M140 CARTRIDGE STRAP NOTE: SHORT SIDE INWARD QTY 2 REQ'D

(26) C09387 TRIKON KNOB QTY 2 REQ'D  
C08002 LOCITITE RED A/R

(12) C09472 SCREW, WOOD FLAT HD #8 x 1.25 LG QTY 12 REQ'D

(11) 132-502-M316 TRAP WEDGE QTY 4 REQ'D

(31) C09494 BAND CLAMP, 7/16 - 15/16 4PL

C09370 PULL HANDLE QTY 2 REQ'D

C09363 TRAY SUPPORT, R.H.

132-502-M312 UPPER TRAY MFG BRKT QTY 2 REQ'D

(49)

C09196 SCR STD HD, 1/4-20x.50 QTY 4 REQ'D  
C08002 LOCITITE BLUE A/R

132-502-L002 LABEL, AIR FLOW

C09380 INSULATION GROMMET

(50)

C09374 DOOR LATCH QTY 2 REQ'D  
C09248 SCR PIN 6-32x.375 QTY 2 REQ'D  
C08002 LOCITITE BLUE A/R

C10051 DOME PLUG .50 DIA.

(53) 132-502-M315 PATIENT FEED THRU 2PL

(52) 22 mm END CAP

132-502-M328 7/8" BULKHEAD FITTING

(56)

C09514 PC21, NYLON PANEL NUT

TIE UP EXTRA SLACK WITH WIRE TIE AND CABLE TIE MOUNT (C09010) TO INSIDE WALL.

139-680 FLEXIBLE CORRUGATED TUBING (2) SECTIONS = 12.0' REF  
NOTE: OPPOSITE END TO ITEM #56 BULK-HEAD ADAPTER

139-680 FLEXIBLE CORRUGATED TUBING (2) SECTION = 12.0' REF

132-502-M210 CABINET/LEAD PANEL ASSY.  
CONSISTING OF:  
132-502-M100 LOWER CABINET WELDMENT  
132-502-M133 LEFT LEAD SIDE PANEL  
132-502-M134 LEAD BASE PANEL  
132-502-M135 LEAD BACK PANEL  
132-502-M141 RIGHT LEAD SIDE PANEL  
C09368 CASTER, DUAL WHEEL QTY 4 REQ'D  
C08001 LOCITITE BLUE A/R

132-502-M138 CABINET BASE PLATE QTY 4 REQ'D

## PULMONEX FINAL ASSY 132-503-A000-A



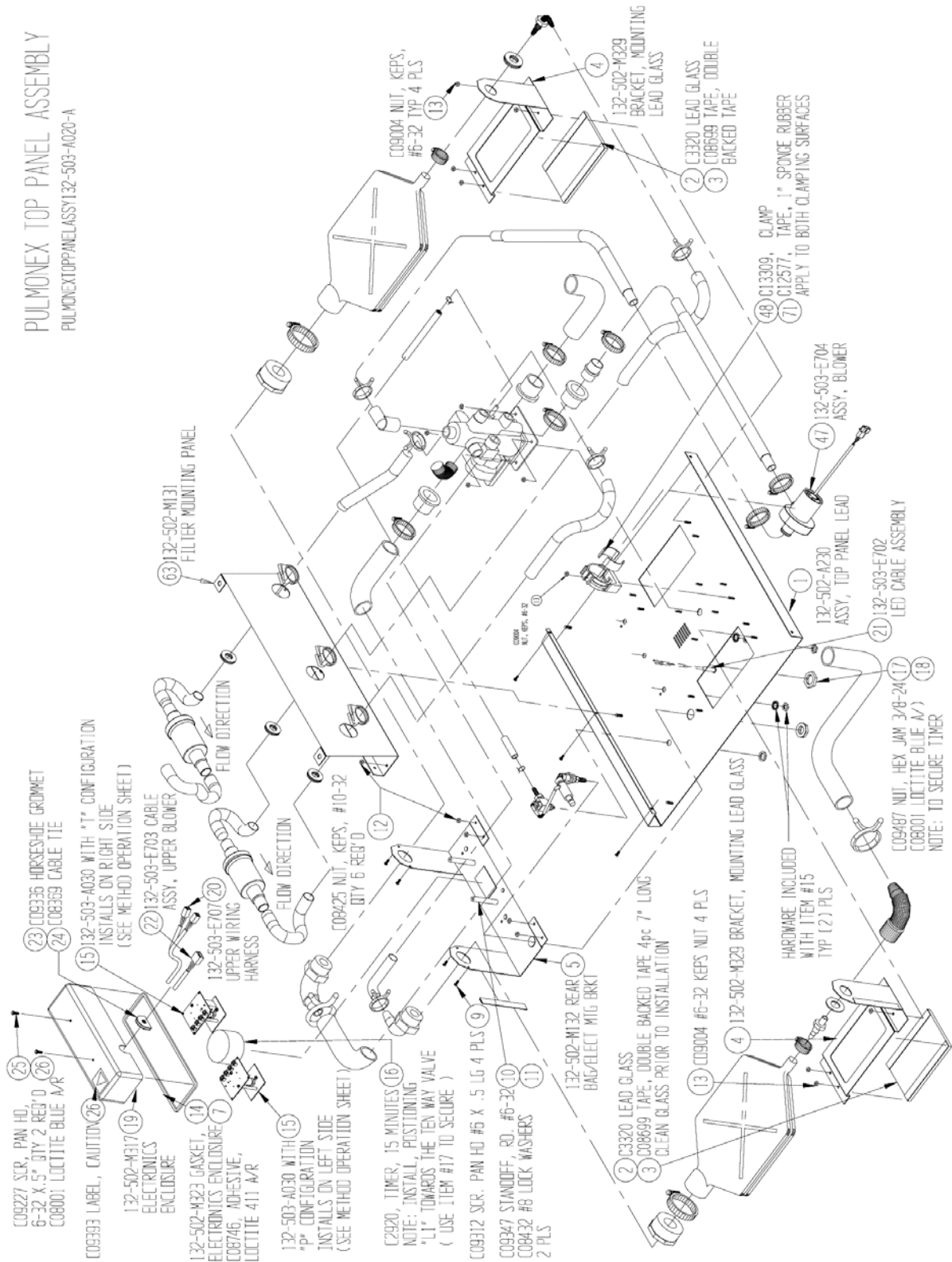


## PULMONEXTOPANEL ASSY132-503-A020-A

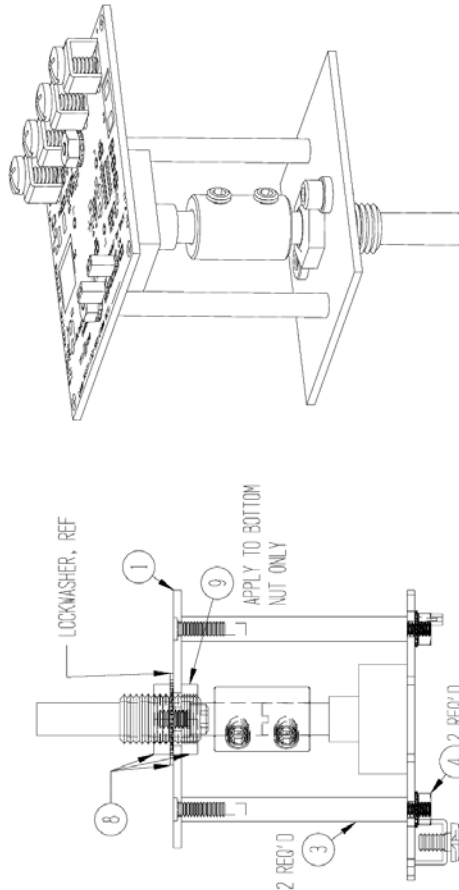
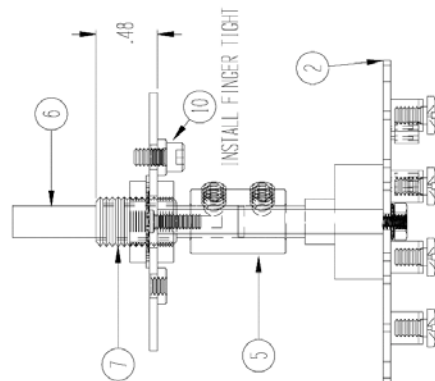
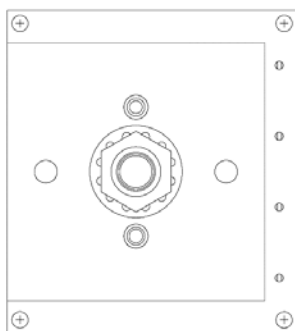




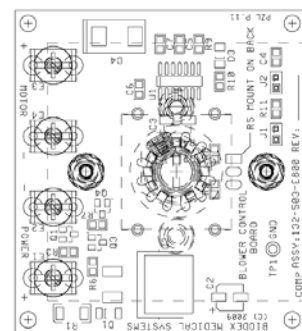
# PULMONEX TOP PANEL ASSEMBLY PULMONEXTOPPANELASSY132-503-A020-A



NOTES:  
IMPORTANT !!  
DO NOT INSTALL WITHOUT REFERRING TO METHOD SHEET FOR FINAL CONFIGURATION

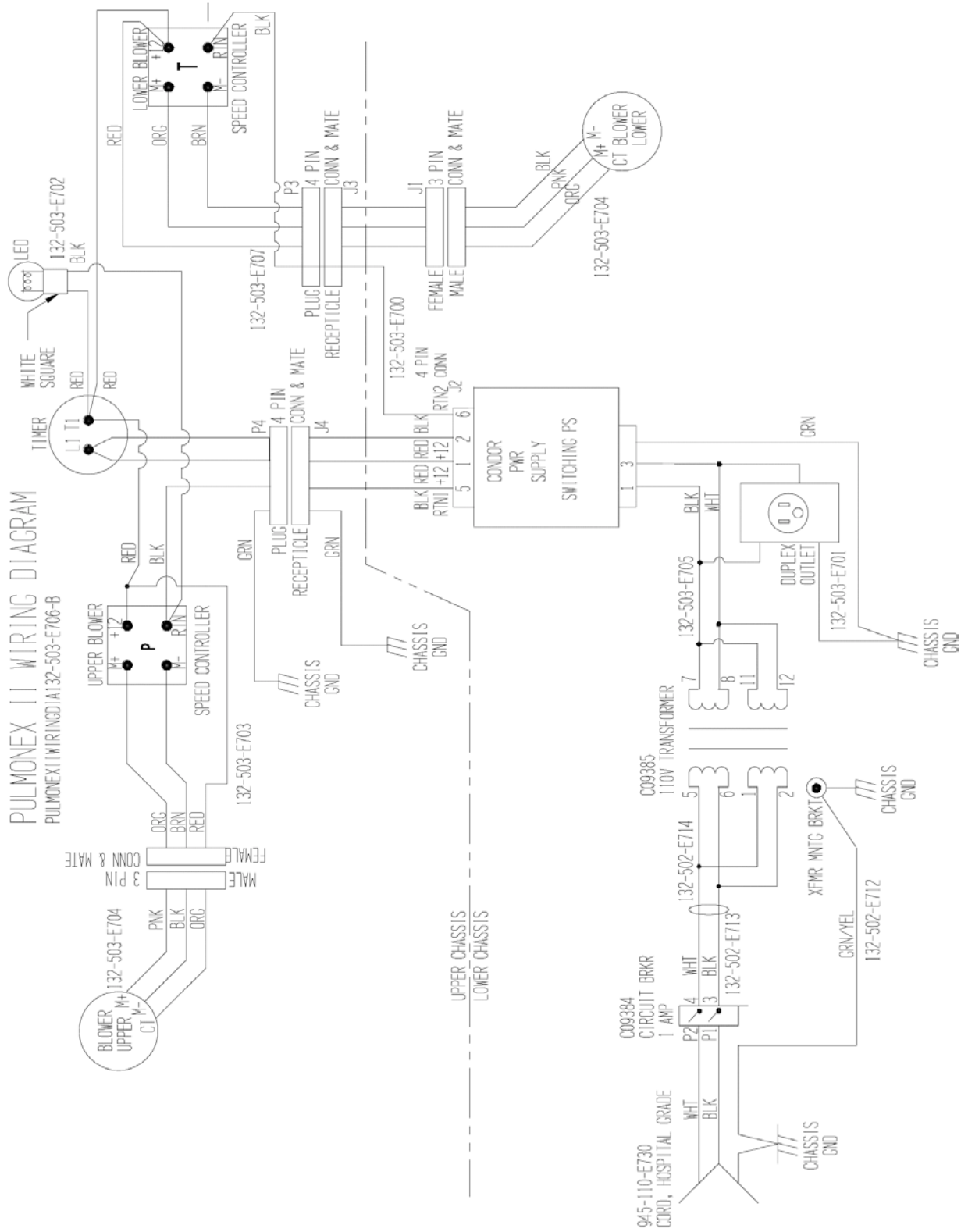


10	1	C11162	SCREW, HEX SKT CAP, 6-32UNC X .25 LG, NYLON
9	A/R	C08001	LOCTITE, BLUE
8	1	C13306	NUTAWASHER SET (USE ONLY (2) NUTS AND (1) LOCKWASHER)
7	1	132-503-W303	SLEEVE, SHAFT
6	1	132-503-W302	EXTENSION, SHAFT
5	1	C13305	COUPLING, 1/4" SHAFT
4	2	C09247	NUT, KEPS, 4-40UNC, ST STL
3	2	C13304	STANDOFF, 1/4" RND, 1.75" LG W/F, 4-40UNC
2	1	132-503-E800	POB, PULMONEX BLOWER CONTROL
1	1	132-503-W301	BRACKET, BLOWER POB MOUNT



# PULMONEX II WIRING DIAGRAM

PULMONEX II WIRING DIAGRAM 132-503-E706-B



# BIODEX

Biodex Medical Systems, Inc.

20 Ramsey Road, Shirley, New York, 11967-4704, Tel: 800-224-6339 (*Int'l 631-924-9000*), Fax: 631-924-9241, Email: [info@biodex.com](mailto:info@biodex.com), [www.biodex.com](http://www.biodex.com)

